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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,750	05/03/2007	Justin P. Phillips	45852-P001WOUS	7003
61060	7590	09/24/2008	EXAMINER	
WINSTEAD PC			BERHANU, ETSUB D	
P.O. BOX 50784			ART UNIT	PAPER NUMBER
DALLAS, TX 75201			3768	
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		09/24/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,750	PHILLIPS ET AL.	
	Examiner	Art Unit	
	ETSUB D. BERHANU	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 9-16 is/are pending in the application.
 - 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 9-16 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 June 2006 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>6/21/06 11/15/06</u>	6) <input type="checkbox"/> Other: ____ .

DETAILED ACTION

Claim Objections

1. Claims 9-15 are objected to because of the following informalities: it is unclear if the first optical fibre in claim 9 is intended to have only one of the light sources adjacent its proximal end, as the means for determining the oxygen saturation level requires measurements from both light sources; the term - - fibres - - should be inserted after the term "optical" in line 2 of claim 15; the term - - an - - should be inserted between the terms "of" and "apparatus" in line 3 of claim 16; it is unclear whether Applicant intended to include both the "the" term and the "said" term in the phrase "the said second optical fibre" in line 10 of claim 16. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Keller et al.'592 (cited by Applicant).

Keller et al.'592 discloses an apparatus for measuring the oxygen saturation level of blood at an internal measurement site, the internal measurement site being the brain, by reflectance pulse oximetry, the apparatus comprising: a first monochromatic light source having a first spectral distribution, a second monochromatic light source having a second spectral distribution, a first optical fiber having a proximal end adjacent at least one said light source and a distal end adapted in use to be positioned adjacent said internal measurement site, at least one receiver, at least a second optical fiber having a proximal end

adjacent the said receiver and a distal end adapted in use to be positioned adjacent said internal measurement site, and means for determining the oxygen saturation level of the blood at the internal measurement site, wherein the optical centers of the first and second optical fibers are separated from one another by at least 1 mm at their distal ends (page 6, lines 14-24, page 7, line 25 – page 8, line 26, page 9, line 6 – page 10, line 3), and wherein the first monochromatic light source is capable of producing light having a peak emission wavelength of from 630nm to 760nm and the second light source is capable of producing light having a peak emission wavelength of from 820nm to 930nm (see claims 17 and 18). Keller et al.'592 further discloses means for pulsing light from the first and second light sources sequentially along the first optical fiber (see Figure 4, element 27 and page 12, lines 21-31). The above cited sections of Keller et al.'592 also disclose a method of measuring the oxygen saturation level in the brain tissue of a human, wherein the steps comprise inserting the distal ends of the optical fibers of the apparatus discussed above through a cranial access hole positioned in the skull of a patient, illuminating the brain surface of the patient using said light sources and determining the oxygen saturation level of blood at the brain from reflected light received at the receiver via the second optical fiber. Figures 8 and 9 indicate that the distal ends of the optical fibers are placed at a distance from 0 to 4.0mm from the brain surface.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al.'592, as applied to claim 9, further in view of Miller et al.'774 (cited by Applicant).

Keller et al.'592 discloses all the elements of the current invention, as discussed in paragraph 3 above, except for the apparatus comprising a cranial access bolt and means for supporting the optical fibers in the access bolt. Miller et al.'774 teaches that it is well known in the art to implement a cranial access bolt and support means to stabilize and secure a fiberoptic probe for accurate placement of a fiberoptic probe and to maintain intracranial sterility (col. 8, lines 28-55 and col. 14, line 65 - col. 15, line 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus and method of Keller et al.'592 to include a cranial access bolt and means for supporting the optical fibers in the access bolt, as taught by Miller et al.'774 since it would stabilize and secure the apparatus for accurate placement of the apparatus within the internal measurement site and also maintain intracranial sterility. Regarding claim 15, it is noted that the distal ends of the optical fibers are capable of being positioned from 0 to 4.0mm from the surface of the brain.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al.'592 further in view of Miller et al.'774.

See the rejection set forth in paragraph 5 above.

7. Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al.'774 further in view of Keller et al.'592.

Miller et al.'774 discloses an apparatus and method for monitoring local cerebral physiology (see TITLE), wherein the apparatus comprises an oximetry probe, a cranial access bolt and means for supporting optical fibers of the apparatus (col. 8, lines 28-55 and col. 14, line 65 – col. 15, line 4) and the method is capable of measuring an oxygen saturation level of the brain by inserting the apparatus into the cranial access bolt (see ABSTRACT, col. 5, lines 20-24 and col. 13, lines 17-37). Miller et al.'774 discloses all the elements of the current invention except for the details of the oximetry probe, specifically a first monochromatic light source, a second monochromatic light source, a first and second optical fiber, a receiver, means for determining the oxygen saturation level of the blood and means for pulsing each

light source. It would have been within the skill of the art to use the oximetry probe of Keller et al.'592 as the oximetry probe of Miller et al.'774 since Miller et al.'774 discloses an intracranial oximetry probe, but fails to give the details of the oximetry probe, and Keller et al.'592 discloses the details of an optical oximetry probe, such as the one discussed in paragraph 3 above, that is capable of being used as the oximetry probe of Miller et al.'774

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marshall'907 (cited by Applicant), Bailey'524 (USPN 5,048,524), Patel et al.'211 (US Pub No. 2004/0059211), Quinn et al.'654 (USPN 6,036,654) and Kohl et al.'600 (USPN 6,961,600) each disclose an apparatus capable of measuring the oxygen saturation level of blood at an internal measurement site by reflectance pulse oximetry.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

EDB